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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,724	05/23/2000	Vladka Curin-Serbec	201196/50 (80242/US)	3140

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	17

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/576,724	CURIN-SERBEC, VLADKA	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10,12-15,17,18,20- 31* is/are pending in the application.

4a) Of the above claim(s) *10,15,17,18 and 21-31* is/are withdrawn from consideration.

5)☒ Claim(s) *6 and 14* is/are allowed.

6)☒ Claim(s) *1-5, 12, 13, 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Amendment filed July 26, 2002 (Paper No. 16) in response to the Office Action of April 23, 2002 is acknowledged and has been entered. Claims 1-5, 12-14 and 20 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** because according to applicant's argument the "three dimensional conformation" refers to native prion protein. Applicant refers to the specification which does not mention any denaturation step when utilizing the antibody. The specification on page 10 lines 22-27 indicates that the antibodies are obtained by immunizing the animals with the peptides of SEQ ID NO: 1 and 2. Following applicants rational, these peptides must have the requisite "thee dimensional conformation".

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**.

The rejection of claims 6 and 14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is withdrawn** in view of applicant's statement that all restriction will be removed upon issuance of a patent and the deposit will be made available to the public.

The rejection of claims 1-5, 12, 13 and 20 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specifically disclosed monoclonal antibody produced by the hybridoma CNCM- I-2476, does not reasonably provide enablement for other antibodies that are able to bind the prion specific protein structure while not binding the normal cellular form of the prion protein **is maintained** for reasons of record.

Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues that the instant invention provides the critical "three dimensional structure" that is different from the prior art and it is therefore predictable that other antibodies which have the quality of binding the disease specific form of the prion protein while not binding the cellular form of the prion protein may be obtained. The antibodies of the invention are produced by linking by peptides to a carrier molecule, in this case KLH and injecting this mixture into an animal.

Fishleigh et al. (U.S. Pat. No. 5,773,572) disclose antibodies that are made via the same methods as the antibody of the instant invention, using peptides comprising the "critical three dimensional structure" of SEQ ID 1 and 2 (Fishleigh et al. SEQ ID NO: 37 and 48; see columns 19-21 and table III [especially VIIIb = SEQ ID 48 peptide]). The antibodies of Fishleigh et al.

all are able to bind the normal prion protein and do not specifically bind the diseased form. It is clear that making antibodies that only recognize the diseased form is not a trivial enterprise which can be achieved using a repeatable method. The peptides following applicant's argument should have the "critical three dimensional structure", yet Fishleigh et al. was not able to produce antibodies that only recognize the native disease specific form. To reiterate Fishleigh et al. clearly set out that using the same methods as those disclosed in the instant invention one of ordinary skill in the art will not be not be able to predictably make an antibody that as the requisite binding requirement of only being able to recognize native disease specific prion protein. Therefore, applicant is enabled only for the single disclosed antibody made from the CNCM- I-2476 hybridoma.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 3-5, 13 and 20 under 35 U.S.C. 102(e) as being anticipated by O'Rourke (U.S. Pat. No. 6,261,790 B1) **is maintained** for reasons of record.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the instant claim does not exclude an unmasking or denaturation step) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, the instant invention rejected as being anticipated by O'Rourke et al.

The rejection of claims 1, 2, 4, 5, 12, 13 and 20 under 35 U.S.C. 102(b) as being anticipated by Prusiner et al. (U.S. Pat. No. 5,846,533) **is maintained** for reasons of record.

Applicant's arguments are that the reference does not utilize competitive binding assays or controls in the ELISA or Western Blot assays. Applicant is reminded that a patent is presumed valid for what it shows. Applicant further asserts that the antibody of the reference column 4, line 45-50 requires a denaturation step by a protease. Applicant's arguments are not persuasive as they do not take in the reference for what it teaches as a whole. The Prusisner et al. reference is directed to a method of making antibodies that recognize the disease specific prion protein while not recognizing the the cellular prion protein applicant is directed to column 35, lines 15-16, column 37, lines 20, and example 18 which describes immunoprecipitation with antibodies directed to disease specific prion protein that are not denatured. Therefore, the instant invention rejected as beiing anticipated by Prusiner et al.

Allowable subject matter

Claims limited to the specific monoclonal antibody derived from the CNCM- I-2476 hybridoma cell line would be allowable.

Conclusion

Claims 6 and 14 would be allowable if rewritten in independent form.

Claims 1-5, 12, 13 and 20 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JAMES HOUSEL 10/20/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600